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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,158	12/30/1999	Thomas J. Gardella	0609.4780001	6018

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WASHINGTON, DC 20005

EXAMINER
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LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/475,158

Applicant(s)

GARDELLA ET AL.

Examiner

Ruixiang Li

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-11, 14 and 37.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

CHRISTINE J. SAUD  
PRIMARY EXAMINER

*Christine J. Saud*

Continuation of 2. NOTE: the amended claim 1 has added, in part, the following limitations: (i) wherein said compound has a biological activity substantially similar to PTH(1-34) or PTHrP(1-34); and (ii) wherein said linker is selected from the group comprising an amino acid and an aliphatic diamine. The limitation (i) raises the issue of indefiniteness under 35 U.S.C. 112, 2nd paragraph since the term "substantially" is not defined in the specification and it is not clear what are the metes and bounds of the term, rendering the claim indefinite. Limitation (ii) raises a new issue, which requires new search and consideration.

Furthermore, the proposed amendment presents two new claims without canceling a corresponding number of finally rejected claims.

Continuation of 5. does NOT place the application in condition for allowance because: the rejection of claims 1-11, 14, and 37 under 35 U.S.C. 112, 1st paragraph for scope of enablement remains.

Applicants argue that Applicants have amended the claim 1 to address the Examiner's concerns that there is no specific functional limitation for the claimed compounds. This is not persuasive because the the newly added limitation does not define a specific, meaningful biological function. In addition, the limitation raised an indefiniteness issue as noted above.

Applicants argue that Applicants have amended the claim 1 to overcome the rejection over the issue of the undefined linker. This is not persuasive because the scope of the linker recited in the amended claim is still too broad. Needless to say the type of the linker, even the length of the linker is undefined.